Intended for UK healthcare professionals

Prescribing information can be accessed HERE

Relief from nausea and vomiting during pregnancy

Xonvea®

doxylamine succinate/
pyridoxine hydrochloride

Pregnancy sickness is the last thing she craves...

XONVEA® is indicated for the treatment of nausea and vomiting of pregnancy (NVP) in pregnant women ≥ 18 years who do not respond to conservative management.[1]

CLICK HERE to visit the XONVEA® promotional website

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. Adverse events should also be reported to Exeltis UK Limited by email to pharmacovigilance.uk@exeltis.com

Exeltis
Rethinking healthcare.
Rethinking women's health.

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NVP affects the majority of pregnant women[2-4]

Up to 85%

of women experience at least one symptom of NVP during their pregnancy[2]

Week 9

of pregnancy is when symptoms typically peak, with symptoms ceasing for 90% of women by week 16[2,3]

NVP can have a broad impact on quality of life[5]

In a 2012 U.S. online National Consumer Survey in pregnant women (n=621), various impacts of NVP (affecting >65% of respondents) on domestic and social life were reported:

71%

Responsibilities - taking care of household chores (n=441)

68%

Family life - enjoying activities with family and friends (n=422)

67%

Social life - willingness or motivation to be socially active (n=416)

66%

Relationships - intimacy with partner (n=410)

66%

Productivity - concentrating on tasks (n=410)

Online survey of pregnant women in the US (n = 621) conducted in 2012. Respondents were at least 16 weeks pregnant or had given birth within the past 6 months, had experienced nausea and/or vomiting during their current or recent pregnancy, and had received routine prenatal care. In all cases, the impact of NVP was significantly more prevalent in women with moderate/severe NVP than those with mild NVP ($P<0.05$).[5]

XONVEA® is the only UK licensed product with a specific indication in NVP for ≥18 years of age[1]

~615,525

the number of pregnancies in which XONVEA® has been prescribed (global usage data for the three years Feb 2020 – Jan 2023)[7]

XONVEA® is backed by ~70 years of global experience with the use of doxylamine/ pyridoxine combination products to treat NVP, with the first combination product introduced in 1956.[6]

Care should be taken when prescribing in pregnancy as medicines can cross the placenta and may affect the fetus. Always refer to the full Summary of Product Characteristics prior to prescribing.

How to take XONVEA®[1]

Day 1 - Starting Dose			
Morning ✗	**Mid-afternoon** ✗	**Bedtime** Take 2 x tablets ✓	Continue with this dose and review symptoms on the afternoon of Day 2.
Day 2			
Morning ✗	**Mid-afternoon** ✗	**Bedtime** Take 2 x tablets ✓	If symptoms continue past the afternoon of Day 2, move to Day 3 dose. Otherwise, continue with this dose throughout.
Day 3			
Morning Take 1 x tablet ✓	**Mid-afternoon** ✗	**Bedtime** Take 2 x tablets ✓	If symptoms continue on Day 3, move to maximum dose. Otherwise, continue with this dose throughout.
Day 4 - Maximum Dose			
Morning Take 1 x tablet ✓	**Mid-afternoon** Take 1 x tablet ✓	**Bedtime** Take 2 x tablets ✓	The continued need for XONVEA® should be assessed regularly throughout pregnancy.

MAXIMUM DOSE: 4 tablets daily

Take daily and NOT on an as needed basis

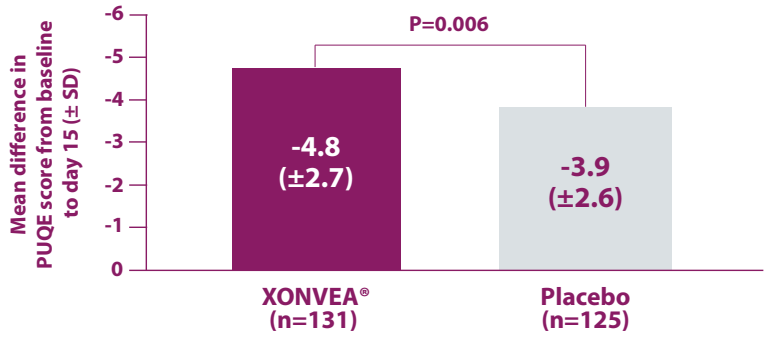
When discontinuing, gradually taper dose to prevent sudden return of NVP symptoms

XONVEA® can help manage the symptoms of NVP and can improve quality of life[8]

A randomised, double-blind, multicentre, placebo-controlled Phase 3 trial studied XONVEA® in pregnant women experiencing symptoms of NVP.

Primary effectiveness endpoint - symptom control

Changes in PUQE score from baseline to day 15[8]



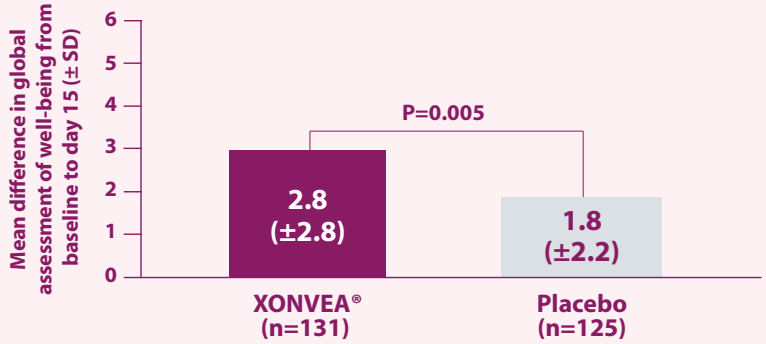
Adapted from Koren *et al.* 2010.

XONVEA® delivered a **4.8-point reduction in the pregnancy-unique quantification of emesis (PUQE)** score by day 15[8]

PUQE score	XONVEA®	Placebo	Treatment difference [95% Confidence Interval]
Baseline	9.0±2.1	8.8±2.1	
Change from baseline at Day 15	-4.8±2.7	-3.9±2.6	-0.9 [-1.2, -0.2]
The PUQE score incorporates the number of daily vomiting episodes, number of daily heaves, and length of daily nausea in hours, for an overall score of symptoms rated from 3 (no symptoms) to 15 (most severe).			

Secondary effectiveness endpoint - quality of life

Changes in global assessment of well-being score from baseline to day 15[8]



Adapted from Koren *et al.* 2010.

XONVEA® delivered a **2.8-point increase in the global assessment of well-being score** by day 15[8]

Global assessment of well-being	XONVEA®	Placebo
Baseline	5.0±2.3	5.4±2.2
Change from baseline at Day 15	2.8±2.8	1.8±2.2
Reference scale for well-being: 0 (worst possible) to 10 (the best you felt before pregnancy).		

Data shown are the intention to treat population, inclusive of any subject who took at least one dose of study medication and had at least one post-baseline PUQE measurement.

XONVEA® is generally well-tolerated[1]

In the Phase 3 clinical trial, use of XONVEA® was not associated with an increased rate of any adverse event (AE) as compared with placebo (all differences were non-significant).[8]

Additional AEs of unknown frequency: hypersensitivity, anxiety, disorientation, insomnia, nightmares, headache, migraine, parasthesia, psychomotor hyperactivity, blurred vision, visual disturbances, vertigo, dyspnea, palpitation, tachycardia, abdominal distention, abdominal pain, constipation, diarrhoea, hyperhidrosis, pruritus, rash, maculo-papular rash, dysuria, urinary retention, chest discomfort, irritability, malaise.

XONVEA® may cause somnolence due to the anticholinergic properties of doxylamine succinate, an antihistamine. XONVEA® has a moderate to major influence on the ability to drive and use machines. **Women should avoid such activities while using XONVEA® until cleared to do so by their healthcare professional.[1]**

Care should be taken when prescribing in pregnancy as medicines can cross the placenta and may affect the fetus. Always refer to the full Summary of Product Characteristics prior to prescribing.

AEs experienced with XONVEA®[1]

AE	Frequency
Somnolence	Very common
Dizziness	Common
Dry mouth	Common
Fatigue	Common

Very common (≥1/10); common (≥1/100 to <1/10)

XONVEA® in fertility, pregnancy, and lactation[1]

A large amount of data in pregnant women indicated no malformative nor feto/neonatal toxicity of doxylamine succinate and pyridoxine hydrochloride in the first trimester

About XONVEA®

XONVEA® is the only UK licensed product with a specific indication in NVP for ≥18 years of age[1]

Significant reduction in PUQE symptom domain score from baseline compared to placebo at Day 15 (p=0.006)[8]

In the Phase 3 clinical study, XONVEA® was generally well-tolerated[8]

- Incidence of treatment emergent adverse events was similar for both treatment and placebo groups
- The most frequently reported AE (≥5% and exceeding the rate in placebo) was somnolence

Contraindications, special warnings and precautions for use

Contraindications[1]

- Hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any of the excipients listed in section 6.1 of the Summary of Product Characteristics.
- Concomitant use with monoamine oxidase inhibitors (MAOIs).

Special warnings and precautions for use[1]

- Limited evidence in cases of hyperemesis gravidarum for the combination doxylamine succinate/pyridoxine hydrochloride. These patients should be treated by a specialist.
- May cause somnolence due to the anticholinergic properties of doxylamine succinate, an antihistamine.
- XONVEA® has anticholinergic properties and, therefore, should be used with caution in patients with: asthma, increased intraocular pressure, narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction and bladder-neck obstruction.
- XONVEA® contains pyridoxine hydrochloride, a vitamin B6 analogue, therefore additional levels from diet and vitamin B6 supplements should be assessed.
- There have been reports of false positive urine screening tests for methadone, opiates and phencyclidine phosphate with doxylamine succinate/pyridoxine hydrochloride use.
- XONVEA® contains traces of the azo colouring agent Allura Red AC Aluminum Lake (E129) which may cause allergic reactions.

XONVEA® may have a moderate to major impact on a woman's ability to drive. Please advise patients on the risks of driving while taking XONVEA® before prescribing.[1]

Interactions

Monoamine oxidase inhibitors[1]

- Monoamine oxidase inhibitors prolong and intensify the anticholinergic effects of antihistamines and concomitant treatment with MAOIs is contraindicated.

Central nervous system depressants[1]

- Concurrent use with central nervous system depressants including alcohol, hypnotic sedatives and tranquillisers is not recommended. The combination may result in severe drowsiness.

Food[1]

- A food-effect study has demonstrated that the delay in the onset of action of XONVEA® may be further delayed, and a reduction in absorption may occur when tablets are taken with food.
- Therefore, XONVEA® should be taken on an empty stomach with a glass of water (see section 4.2 of Summary of Product Characteristics).

Interference with urine screen for methadone, opiates and PCP[1]

- False positive urine drug screens for methadone, opiates, and phencyclidine phosphate (PCP) can occur with doxylamine succinate/pyridoxine hydrochloride use. Confirmatory tests, such as Gas Chromatography Mass Spectrometry (GC-MS), should be used to confirm the identity of the substance in the event of a positive immunoassay result.

**CLICK HERE to view XONVEA®
(doxylamine succinate/pyridoxine hydrochloride)
prescribing information. Consult the Summary of
Product Characteristics before prescribing.**

Xonvea®

doxylamine succinate/
pyridoxine hydrochloride

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Abbreviations:
AE, adverse event; CNS, central nervous system; GC-MS, Gas Chromatography Mass Spectrometry; MAOIs, monoamine oxidase inhibitors; NVP, nausea and vomiting of pregnancy; PCP, phencyclidine phosphate; PUQE, pregnancy-unique quantification of emesis; SD, standard deviation; UK, United Kingdom; US, United States.

References:

1. XONVEA® Summary of Product Characteristics.
2. Whitehead, S.A., *et al. J Obstet and Gynaecol.* 1992; 12(6):364-369.
3. Gadsby, R., *et al. Br J Gen Prac.* 1993;43:245-248.
4. Lacroix, R,. *et al. Am J Obstet Gynecol.* 2000;182:931-7.
5. Clark, S., *et al. Obstet Gynecol Surv.* 2013;68:S1-S10.
6. Madjunkova, S., *et al. Paediatr Drugs.* 2014;16:199-211.
7. Exeltis data on file XON03.
8. Koren, G., *et al. Am J Obstet Gynecol.* 2010;203(6):571.e1-571.e7.

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